JUN 2 3 2005

K050903

Premarket Notification 510 (k)
Xavex G100

WIELAND
Dental + Technik

Wieland Dental + Technik
GmbH & Co. KG
Schwenninger Straße 13
D-75179 Pforzheim

5. 510 (k) Summary

Submitter of 510(k):	Wieland Dental + Technik GmbH & Co. KG Schwenninger Str. 13 D-75179 Pforzheim Germany Phone: +49-7231-3705-0
Contact person:	Dr. Gerhard Polzer
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e-mail:	gerhard.polzer@wieland-dental.de
Date of Summary:	2005-04-07
Trade name:	Xavex G100
Classification name:	Porcelain powder for clinical use
Product code:	EIH
C.D.R section:	872.6660
Classification:	Class II
Legally marketed equivalent device:	Cercon Base
510(k) number:	K013230

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510 (k) Summary

Device description

Xavex G100 is a dental ceramic that is composed of partially sintered yttria (yttrium oxide) stabilized zirconium oxide.

Xavex G100 is designed for manufacturing substructures of all-ceramic dental appliances for the sole use of particular patients. It has to be machined with the CAD/CAM technique and then sintered to its full density.

Xavex G100 is designed for use as single tooth or bridgeworks with up to two pontics in the anterior as well as the posterior teeth region.

Xavex G100 is biocompatible and insoluble in water. In addition, the strength of densely sintered Zirconium oxide is extremely high and makes delicate and filigree framework shaping possible. This, together with the white color of the zirconium oxide offers the basis for aesthetically pleasing, safe and effective dental restorations.

Xavex G100 substructures can be veneered with suitable dental porcelains with the layering technique.

Xavex G100 meets all applicable requirements of the standard ISO 6872: 1997 "Dental ceramic".

The partially sintered Xavex G100 blanks will be offered as disks with a diameter of 100 mm and 5 different thicknesses:

Xavex G100-25 with a thickness of 25 mm
Xavex G100-20 with a thickness of 20 mm
Xavex G100-18 with a thickness of 18 mm
Xavex G100-14 with a thickness of 14 mm
Xavex G100-10 with a thickness of 10 mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2005

Dr. Gerhard Polzer
Director Regulatory Affairs
Wieland Dental +Technik GmbH & Company KG
Schwenninger Strasse 13
D-75179 Pforzheim
GERMANY

Re: K050903
Trade/Device Name: Xavex G100
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: April 8, 2005
Received: April 11, 2005

Dear Mr. Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

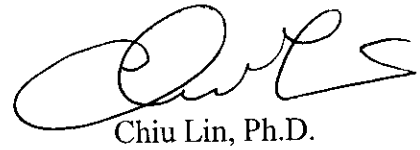
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Xavex G100**

Indications For Use:

Xavex G100 is a dental ceramic that can be used by dental technicians to fabricate all-ceramic restorations. It is a partially sintered yttria stabilized zirconium oxide powder that has to be machined with the CAD/CAM technique to its required shape and then sintered to full density.

Xavex G100 is recommended for manufacturing substructures of single tooth and bridgework with up to two pontics, which can be used in the anterior as well as in the posterior tooth region.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K050903